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October 10, 2019

VIA ECF

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets, Courtroom 3C
Camden, NJ 08101

Re: In re Valsartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Schneider:

This letter is to provide Defendants' position with respect to the topics addressed in Plaintiffs' letter in advance of the Case Management Conference with the Court this afternoon. Given that yesterday was one of the Jewish High Holidays, which the Court explicitly scheduled around at the last CMC, and because the Court had set the limited agenda for today's call in CMO 14 (Dkt. 243), Defendants did not anticipate the letter Plaintiffs filed yesterday. However, that letter is strewn with misrepresentations and hyperbole that require this response.

1. The October 7 Meet and Confer[1]

The purpose of the joint meeting on October 7 was for the parties to begin a collaborative process that would hopefully produce a list of employees from each Manufacturer Defendant that would comprise the ESI custodians for which documents responsive to Plaintiffs' document requests would be searched,[2] without the need for burdening a corporate representative with meeting with Plaintiffs' counsel in New Jersey to provide information about the Defendants and their employees that the defense counsel could just as easily provide. The meeting was also to be used to begin to discuss the search terms that would be employed in the ESI collection, and to identify common issues overlapping the Manufacturer Defendants with respect to ESI custodians and search terms.

As this case concerns an alleged impurity purportedly arising out of a specific chemical reaction occurring during a step in the valsartan manufacturing process, on September 23 the Manufacturer Defendants each proposed ESI custodians whom they understood from interviewing their respective clients, were closely involved with the manufacturing processes, testing and regulatory functions at issue, and thus were more likely to be in possession of relevant ESI and other documents. Despite having had the Manufacturer Defendants' proposed custodian lists since

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1 The joint meet and confer started at 10:00 a.m. and ended at 3:00 p.m. In addition to counsel for ZHP, Mylan, Teva, Torrent, Aurolife, and Hetero USA, eight Plaintiffs' counsel attended in person, and one attended by phone.

2 Plaintiffs' document requests are entitled "Plaintiffs' First Set of Requests for Production of Documents ***to All API and Finished-Dose Manufacturer Defendants***." (emphasis added). Accordingly, only the Manufacturer Defendants participated in the October 7 meeting, and distributors and retailers neither attended the meeting nor proposed custodians.

September 23, and despite the Court's agreeing on October 1 that Defendants' suggestion of a joint meet and confer was a good idea, Plaintiffs did not provide a list of topics to be discussed at the meeting until nearly 11:00 p.m. on Thursday, October 3.

While Defendants' counsel were already hard at work preparing for the meeting by discussing with their clients their respective corporate organizational structures, departments and divisions, and employees, Plaintiffs left Defendants with only a single business day to communicate with clients about any of the 23 topics set forth in Plaintiffs' 11-page letter. This timeline was further complicated by the fact that many of the Manufacturer Defendants are foreign companies located many time zones ahead. Importantly, *Plaintiffs' letter did not identify any employee of any Defendant that Plaintiffs proposed as an ESI custodian*, and at no time prior to the meet and confer did Plaintiffs ever make such proposal.

Notwithstanding the late arrival of Plaintiffs' letter, defense counsel for each of the Manufacturer Defendants had collected, and were prepared to discuss, information from their clients related to virtually all of the 23 topics set forth in Plaintiffs' letter, including their respective internal corporate structure, department and division responsibilities, and the ESI custodians proposed on September 23, as well as certain additional potential custodians.[3] Counsel were also

[3] Plaintiffs place a great deal of emphasis on Defendants' corporate organization charts, as if an ESI custodian list cannot be compiled without one. However, no Defendant is withholding an organizational chart. To the contrary, Defendants have either agreed to provide an organizational chart, stated that their client does not maintain such a chart, or have explained that they are still confirming whether such a chart exists. Plaintiffs misrepresent counsel's response related to organizational charts. ZHP does not intend to withhold a corporate organization chart, if one is maintained in ZHP's ordinary course of business, until formally responding to Plaintiffs' document requests. Rather, counsel stated that counsel is still confirming whether ZHP maintains an organizational chart showing all relevant departments, but was unable to so confirm due to a Chinese National

prepared to, and did, provide information on the sizes of batches and lots of valsartan API and finished doses.

After spending the first 30 minutes discussing lot and batch sizes, which vary among the Manufacturer Defendants, Plaintiffs focused their inquiry on ZHP. For approximately three hours, each of the eight Plaintiffs' counsel attending in person haphazardly asked questions about virtually every aspect of ZHP's business, often asking questions over one another about different topics, and even before questions were answered, without any apparent rhyme or reason, and often without any meaningful connection to valsartan or the alleged NDMA and NDEA impurities. For example, Plaintiffs' counsel was insistent that ZHP should identify the *employee who affixes the stickers on the containers of API*. Similarly, when asked for reference to documents produced during Core Discovery to substantiate the Plaintiffs' nomination of additional ZHP custodians, Plaintiffs were unable to provide such information

While Plaintiffs portray this inquiry as fruitless, as discussed below, it provided Plaintiffs with a great deal of information about ZHP's operations and the ESI custodians ZHP proposed, as well as provided ZHP's counsel with a list of questions and the identity of additional potential ZHP custodians that ZHP has agreed to follow up on.[4] Indeed, the three hours that the eight

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Holiday which occurred from October 1-7, and resulted in the closure of ZHP's offices in China that week. In fact, Prinston has already produced an organizational chart that was provided to the FDA covering key employees in the Quality Assurance, Quality Control, Analytical Operations, and API Manufacturing departments as part of Core Discovery (PRINSTON0075015).

[4] Significantly, it was not until close to 2:00 pm that Plaintiffs first identified any employees they proposed as additional custodians, despite being asked by ZHP's counsel several times to do so.

Plaintiffs' counsel spent "deposing" ZHP's counsel were so productive Plaintiffs scheduled similar sessions with each of the other Manufacturer Defendants. Those additional meet and confers have occurred telephonically since Monday. After each of the meet and confers, Plaintiffs have sent the Defendant a list of names for consideration as additional potential custodians. Defendants propose that the meet and confers continue to completion.

Underscoring the productivity of this process, each Manufacturer Defendant has agreed to collect additional information about their clients' operations and their employees, including the additional individuals identified by Plaintiffs, and each participating Defendant has agreed to meet with Plaintiffs again to confer about rounding out the ESI custodian lists. Notably, the parties have now collectively identified between 10-30 employees per Manufacturer Defendant who could comprise the list of ESI custodians for that Manufacturer Defendant. A final list of ESI custodians is within striking distance. As happens in virtually every case, additional ESI custodians, if any, could be identified during or after the collection, production and review of documents based on the current list of custodians.

Additionally, it should be noted that, contrary to Plaintiffs' characterization, Plaintiffs' informal meetings with representatives of Defendants in the *Benicar* litigation *did not occur at the ESI custodian selection stage*. Instead, these meetings occurred much later, after ESI custodians had already been decided and when the parties were attempting to identify appropriate individuals for deposition. Defendants believe that, as in *Benicar*, they will be able to obtain the information

necessary to finalize ESI custodian lists without resorting to burdensome meetings between corporate representatives and Plaintiffs' counsel.

2. Defendant-Specific Issues

a. ZHP

Plaintiffs' accusation that ZHP's counsel "was unwilling or unable to provide basic information" is a gross mischaracterization of the October 7 meeting. Dkt. 257 at 2. Contrary to Plaintiffs' representations, counsel endured a three-hour inquiry from nine attending Plaintiffs' counsel firing off questions randomly and haphazardly. Notwithstanding, ZHP's counsel provided substantive information about ZHP's internal organization and proposed custodians, as well as other individuals possibly possessing relevant information. Moreover, despite having had a single business day to evaluate Plaintiffs' 11-page letter of proposed topics, counsel was prepared to address the vast majority of the questions contained therein. Specifically, counsel provided information about the internal organization and responsibilities of relevant departments and sub-departments within ZHP, including: Quality, Quality Assurance, Quality Control, Analytical Operations, API Manufacturing, Technology, Production, Business Development/API Sales, Regulatory Affairs, Finance, and Purchasing.

Counsel also provided context for each of the seven ZHP custodians it proposed to Plaintiffs on September 23. In particular, counsel explained that ZHP's proposed custodians include:

1. Linda Lin, the Head of Regulatory Affairs, who has been compiling and submitting documents to the FDA related to the valsartan recall, and who has attended meetings with the FDA on this topic;

2. Wang Peng, the Senior Director of API Manufacturing, who reports to the President of API Manufacturing and who oversees the manufacture of valsartan API;

3. Dong Peng, the Associate Director of API Manufacturing, who reports to the Senior Director and who was involved in the 2013 manufacturing process change at issue as a former member of the Technology sub-department within API Manufacturing;

4. Jucai Ge, the Director of the API Division of Quality Assurance, who (a) reports to the VP of the Quality Department, (b) has been overseeing the root-cause analysis for NDMA and NDEA impurities, and (c) was involved in the 2013 manufacturing process change at issue from a quality assurance perspective;

5. Qiangming Li, the Director of API Quality Control, who (a) reports to the VP of Analytical Operations, (b) oversees the analytical lab for API, and (c) was involved in the 2013 manufacturing process change at issue from a quality control perspective;

6. Min Li, the VP of Analytical Operations, who oversees the development and implementation of all quality control procedures at ZHP, including establishing analytical methods for Valsartan generally and for identifying nitrosamines specifically; and

7. Jie Wang, the VP of Business Development/API Sales, who is responsible for setting API prices and communicating with customers.

Moreover, based on its meeting preparation, ZHP proposed three new custodians: Lucy Liu and Ting Zhou, two managers in the Regulatory Affairs group who have also communicated with the FDA relating to the impurity and recall, and Yuelin Hu, a manager in the API Division of Quality Assurance who was also involved in the 2013 manufacturing process change at issue. And for each of these proposed custodians, counsel for ZHP endeavored to provide detailed information, including:

- Title and department;
- Length of time they have been employed in their current role;
- Description of their current job responsibilities;
- Description of their involvement with valsartan manufacturing, testing, sale, and/or the recall;
- Type of information each custodian is likely to possess;
- Number of employees that report to each custodian; and

- The custodian's reports and to whom the custodian reports.

To the extent counsel lacked any of this information about a particular custodian, counsel agreed to follow up with their clients.[5]

To be sure, counsel substantiated the involvement of each of ZHP's proposed custodians with facts at issue in this action. Plaintiffs' laundry list of missing information is therefore factually incorrect. Plaintiffs complain, for example, that ZHP's counsel have failed to identify "[w]ho analyzed the manufacturing change that allegedly resulted in valsartan API contamination." Dkt. 257 at 6. But ZHP has proposed ***four*** custodians who were members of the committee that analyzed that process change. Counsel also identified by Bates number (PRINSTON0074792–93) a document produced during Core Discovery identifying members of that committee, as well as each committee member's role in the process change and departmental affiliation.

Counsel also explained to Plaintiffs why Jun Du was not identified as a custodian for ZHP. Mr. Du is the Vice Chairman of ZHP's Board. Although he has received FDA communications and attended an inspection of a ZHP facility, his high-level knowledge of the manufacturing process and testing procedures at issue in this case is not the quality of key information possessed by the specialists in the Regulatory Affairs, API Manufacturing, API Quality Assurance, and API Analytical departments that ZHP has proposed as ESI custodians. In contrast, those custodians

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[5] In the few instances that counsel lacked a piece of information about a particular custodian—for example, in one instance counsel was unsure if one custodian held a different title before January 2012—this was because of the Chinese National Holiday. In the week leading up to the meet and confer, employees of ZHP's U.S. affiliates had to relay some of counsel's more granular questions to Chinese employees, who, because of the Chinese National Holiday and office closures, did not respond before October 7. Counsel is continuing to follow up with its clients to collect this information.

possess the technical knowledge of the valsartan manufacturing process or chromatography testing at issue. That the FDA referred to Mr. Du as the person with "authority to hire/fire (with approval by HR)" employees in an inspection report that *predates the valsartan recall* says nothing about Mr. Du's knowledge of the valsartan recall or nitrosamine impurities. *See* Dkt. 257 at 4 (quoting Establishment Inspection Report for May 2017 inspection). And the fact that Mr. Du, a high ranking executive, provided a statement to Bloomberg related to the recall likewise does not support Plaintiffs' insistence that Mr. Du is somehow "the most knowledgeable person in the company about the valsartan contamination." Dkt. 257 at 4. As stated above, ZHP's proposed custodians already include the individuals with the most detailed and technical knowledge of the manufacturing process, the process change, quality assurance, quality control, and regulatory communications with the FDA.

At bottom, Plaintiffs are dissatisfied because they would like the Manufacturer Defendants to identify *every* employee in *every* department who has had *any* involvement with valsartan at *any* time, up to and including the individual employees who placed labels on drums of API. Because ZHP is a large corporation with over 6,000 employees, over 1,500 of whom are in the API Manufacturing division alone—and because Plaintiffs' proposed relevant time period spans more than a decade—counsel was unable to answer Plaintiffs' granular questions about low-level employees in this *initial* meet and confer; an employee's name on a document that also contains the word "valsartan" or "nitrosamine" does not make that employee an appropriate ESI custodian. Nevertheless, counsel from ZHP came to the meet and confer prepared to discuss their proposed custodians and others, as well as general corporate organization, and have further agreed to follow

up with their clients to gather more information about levels of employees beneath the manager or director level, as well as specific individuals identified by Plaintiffs' counsel.

Plaintiffs also complain that counsel was not prepared to discuss "the organizational structure of ZHP's downstream finished-dose subsidiaries." Dkt. 257 at 5. But Plaintiffs have not directed any document requests towards ZHP's subsidiaries. As explained above, their proposed document requests are directed toward API and finished dose manufacturers. As disclosed in a September 16 letter to Plaintiffs—and as discussed in detail during negotiations of the Short Form Complaint—none of ZHP's U.S. subsidiaries are manufacturers.[6] For that reason, counsel was prepared to discuss custodians for ZHP, but not the domestic distributors. Counsel explained this to Plaintiffs at the October 7 meeting, and reiterated ZHP's relationship with the U.S. subsidiaries, but it also agreed to confer about custodians for the subsidiaries at another, more appropriate, time.

Plaintiffs also omit key context related to the additional individuals they identified as potential custodians. Several times during the three-hour questioning related to ZHP's organizational structure, counsel asked Plaintiffs if they had identified any additional employees within the relevant departments about whom they had questions. Plaintiffs repeatedly stated that they did not have enough information to propose additional custodians and were relying on defense counsel to do so—even though Plaintiffs have possessed over 70,000 pages of Core Discovery productions from Prinston *for over two months*, including testing records that identify by name and position ZHP employees who performed or reviewed the tests. After the lunch break and

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[6] Despite multiple disclosures that Solco Healthcare U.S., LLC, is a distributor, not a manufacturer, Plaintiffs' counsel seemed to believe that Solco was a finished dose manufacturer.

toward the end of the meeting, Plaintiffs finally proposed a hastily prepared list of additional potential custodians. Plaintiffs offered no explanation for why they believed those individuals were important, and could not direct counsel to any particular documents within Prinston's productions that would provide context for a more detailed discussion.[7] Although nearly half of Plaintiffs' proposals are current or former employees of the U.S. subsidiaries and therefore not the topic of this initial meet and confer, counsel agreed to compile information about those individuals. As for the ZHP employees, counsel also agreed to collect additional information from ZHP about the individuals' employment history and involvement with valsartan and to continue conferring about whether they should be included as custodians.

ZHP and its counsel have identified 10 employees they believe have the most involvement with the facts at issue, and Plaintiffs have identified another eight ZHP employees they believe may have relevant information. Based on that list of 18, and upon further discussions about the categories of information ZHP counsel has agreed to inquire about with their clients, the parties should be able to agree on a list of custodians from which ESI should be collected.

b. ***Hetero USA***

Counsel for Hetero USA wishes to clarify several items raised in Plaintiffs' October 9th letter as it relates to Hetero USA. Footnote 3 of Mr. Slater's letter states that "[D]efense counsel has not yet confirmed whether they represent the Hetero entities." Counsel for Hetero USA has repeatedly advised Plaintiffs' counsel (including during the in-person and telephonic meet and

[7] Plaintiffs have since sent ZHP's counsel a written list citing to particular documents.

confer process addressing search terms and custodians) that they only represent Hetero USA and that do not represent either co-Defendant Hetero Labs, Ltd. or co-Defendant Hetero Drugs, Ltd.

Given that Hetero Labs has not been served and presently is not in this litigation and in light of the Court having required core discovery from Hetero USA, in an effort of good faith and cooperation counsel for Hetero USA has participated in the meet and confer process for ESI search terms and custodians and provided a list of proposed custodians on behalf of Hetero USA.

c. ***Mylan***

As alluded to in Plaintiffs' letter, Mylan sent two representatives to the day-long, in-person meet and confer held in Philadelphia on Monday, October 7. Mylan's counsel took the opportunity to provide a general overview of its corporate structure; to explain its rationale for its initial list of ESI custodians; to outline each of those individual's roles with respect to manufacture, distribution, sale, and recall of valsartan-containing medications; to supplement its initial list with an additional five potential custodians; and to address (or take under advisement) questions from Plaintiffs' representatives. To keep the process moving forward, Mylan scheduled a follow-up teleconference with Plaintiffs' counsel to be held the morning of October 10 in order to provide an update regarding Mylan's continuing, good-faith efforts to provide plaintiffs with the information they need to conduct ESI discovery in a meaningful, efficient manner. Simply put, Mylan submits that the meet-and-confer process is ongoing, and it is working. Mylan asks only that the Court allow the parties to continue to work through their differences in advance of the December deadline to finalize the scope of ESI discovery.

d. ***Teva***

Teva met and conferred with Plaintiffs' counsel in-person on October 7, 2019, and by phone on October 8, 2019. Teva is collecting additional information on several areas identified by Plaintiffs during these meet and confers. Following the productive meet and confer teleconference on October 8th, Teva does not anticipate any issues with agreeing to a custodian list by the Court's December 11, 2019, deadline.

With respect to Plaintiffs' complaint in footnote 13 that Teva has failed to produce "unredacted" versions of internal emails identified during Core Discovery, brief clarification may be warranted. The custodian of these emails, Constance Truemper, is included on Teva's custodian list. The emails at issue were withheld, not redacted, and Teva has taken no position on their relevance to the litigation—only that they are clearly not responsive to the Core Discovery order. The Court ordered production of correspondence with the FDA. Internal communications, which neither went to nor were received from the FDA, are obviously not correspondence with the FDA. This issue was raised at the August 14, 2019, in-person conference, where the Court ruled, and both Plaintiffs and Defendants agreed, that these emails would be dealt with during Rule 26 discovery along with the myriad other internal documents which may be relevant to this litigation but were nonetheless not the subject of the Court's core discovery order.

e. ***Aurolife***

Counsel for Aurolife and Aurobindo USA met and conferred with Plaintiffs' counsel in-person on October 7, 2019, and by phone on October 8, 2019. Aurolife and Aurobindo USA are collecting additional information on several areas identified by Plaintiffs during these meet and confers. Following the productive meet and confer teleconference on October 8th, Aurolife and

Aurobindo USA do not anticipate any issues with agreeing to a custodian list by the Court's December 11, 2019, deadline.

f. ***Torrent***

Torrent met and conferred with Plaintiffs' counsel in-person on October 7, 2019, and by phone on October 9, 2019. Torrent is collecting additional information on several areas identified by Plaintiffs during these meet and confers. Following the productive meet and confer teleconference on October 9th, Torrent does not anticipate any issues with agreeing to a custodian list by the Court's December 11, 2019, deadline.

* * *

In short, Plaintiffs' insistence that a meeting with a corporate representative is necessary is both unsupported and premature. Counsel for ZHP provided substantive answers to Plaintiffs' questions for three hours, and have agreed to follow up with ZHP and the U.S. affiliates about the additional questions raised at the meet and confer as well as a list of individuals with potential involvement in the valsartan recall identified by Plaintiffs' counsel. The other Defendants who participated similarly have been working to provide information to Plaintiffs and to follow up with information about new potential custodians and have each had separate meet and confers with Plaintiffs. Plaintiffs' request for a meeting with corporate representatives from ZHP's U.S. affiliates is particularly premature, since Plaintiffs have not yet directed any discovery requests towards those Defendants, those Defendants have not yet proposed custodians, and the parties have not yet conferred about any proposed custodian list.

2. Hetero and Aurobindo Corporate Representative Depositions

Mr. Slater's letter indicates that, with regard to the corporate representative depositions of Hetero and Aurobindo, "[No] response has been received from Hetero USA, Inc." That is not correct. By e-mail dated October 3, 2019 Hetero USA counsel advised Mr. Slater that Hetero USA would be acquiring from Hetero Labs Ltd. and producing the remaining core discovery documents (with the exception of those documents Hetero USA had previously advised Plaintiffs were in Camber Inc.'s possession). As a consequence and as also stated in the October 3, 2019 e-mail to Mr. Slater, Hetero USA counsel advised that there would be no need for the corporate representative deposition of Hetero USA.

With regard to service on Hetero Labs, Ltd. and Hetero Drugs, Ltd. counsel for Hetero USA advised plaintiffs' counsel in that same e-mail of October 3, 2019 that it was "unclear" whether Hetero Drugs, Ltd. had been served and that, to their knowledge, Hetero Labs had not been served.

Counsel for Aurolife and Aurobindo USA emailed Plaintiffs' counsel yesterday to follow up on their meet and confer discussion on Monday regarding the Objections to Plaintiffs' 30(b)(6) Notice. Defense counsel is hopeful that the parties will be able to resolve any disputes prior to the teleconference with the Court.

3. "Macro" Discovery Issues

At this point in time, Defendants have identified the following global discovery issues and reserve the right to identify additional issues:

1. Relevance and Discoverability of Foreign Regulatory Materials and Communications

2. Relevance and Discoverability of Foreign Sales, Marketing, and Agreement Information
3. Scope of Relevant Testing
4. Scope of Health Risk Discovery
5. Relevance of Discovery Into Finished Dose Manufacturing Process
6. Relevant Time Period

4. Defendant Fact Sheets

Defendants served a proposed draft of the Defendant Fact Sheet on Plaintiffs on September 16. Defendants await Plaintiffs' comments or proposed revisions.

5. General Discovery Requests

Defendants received Plaintiffs' First Set of Requests for Production of Documents Directed to API and Finished Dose Manufacturer Defendants on August 30 and are preparing to serve written objections to these requests on October 15.

6. Third-Party Payor Fact Sheet

Defendants sent their comments to Plaintiffs' redlines of the TPP fact sheet to Plaintiffs' counsel on October 4, 2019, and are awaiting Plaintiffs' response. Defendants will be prepared to present any outstanding disputes with respect to this fact sheet to the Court for resolution at the October 16, 2019 CMC, and anticipate the parties may be able to submit an agreed-upon fact sheet in advance.

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

cc: Adam Slater, Esq. (*via email*, *for distribution to Plaintiffs' Counsel*)
Jessica Priselac, Esq. (*via email*, *for distribution to Defendants' Counsel*)
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